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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Nobumasa SUZUKI et al.

Group Art Unit: 3733

Appl. No.

: 10/659,302

Examiner: R. Shaffer

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For

: ROD FIXING APPARATUS FOR VERTEBRA CONNECTING

MEMBER

REQUEST FOR PRE-APPEAL BRIEF REVIEW

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AF
Randolph Building
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Alexandria, VA 22314

Sir:

In response to the Final Official Action dated May 25, 2006, setting forth a three-month shortened statutory period for response to expire on August 25, 2006, and which has been extended to expire on September 25, 2006, Applicants respectfully request a Pre-Appeal Brief Panel to review and withdraw the outstanding rejection set forth in the above mentioned Final Official Action in view of the herein contained remarks.

<u>REMARKS</u>

Claim 1 sets forth a rod fixing apparatus for fixing a rod including, inter alia, a pressure fixing device and "protruding portions configured to eat into the rod portion in both end sides of the circular arc rod engagement portion outside the pressure fixing device, the protruding portions extending in a direction substantially perpendicular to a longitudinal direction of the vertebra connecting

member". Claim 3 sets forth a rod fixing apparatus for fixing a rod including, inter alia, a screw portion, a head portion provided with an engagement portion, and "small projections configured to eat into the rod, the small projections being provided on both sides of the groove portion, the small projections extending in a direction substantially perpendicular to a longitudinal direction of the rod".

Applicants' invention includes the rod portion 7R of the vertebra connection member 7 extending in a longitudinal direction along its axis. The first embodiment of the rod fixing apparatus also includes two protruding portions or small projections 15 (two protruding portions 29 in the second embodiment). Protruding portions 15, 29 are positioned at first and second ends of the rod engagement portion 9 (rod engagement portion 23 in the second embodiment). Accordingly, since the protruding portions 15, 29 are positioned at the ends of the rod engagement portion 9, 23, the protruding portions 15, 29 "eat into the rod portion in both end sides of the circular arc rod engagement portion", as recited in claim 1. The small projections 15, 29 are "configured to eat into the rod, the small projections being provided on both sides of the groove portion", as recited in claim 3. Therefore, since the protruding portions 15, 29 are positioned at the ends of the rod engagement portion 9, 23, the protruding portions 15, 29 eat into the rod portion "outside the pressure fixing device", as recited in claim 1.

Further, as clearly shown in the figures, each protruding portion 15, 29 extends substantially perpendicularly to the longitudinal direction of the vertebra connection member 7. In this regard, each protruding portion 15, 29 extends circumferentially along the rod portion 7A of the vertebra connection member 7,

substantially perpendicular to the longitudinal direction of the rod portion 7A. Thus, each protruding portion 15, 29 extends "in a direction substantially perpendicular to a longitudinal direction of the vertebra connecting member", as recited in claim 1. Each small projection 15, 29 extends "in a direction substantially perpendicular to a longitudinal direction of the rod", as recited in claim 3.

The JACKSON patent discloses an assembly including a bone screw 2 having a U-shaped channel 10. A plurality of ridges 17 are positioned on the lower curved edge of the channel.

However, firstly, the plurality of ridges 17 of JACKSON do not eat into the rod portion in both end sides of the circular arc rod engagement portion. In this regard, the plurality of ridges 17 of JACKSON are positioned so as to cover the entire lower curved edge of the U-shaped channel 10. The ridges 17 of JACKSON are not positioned on the ends of the U-shaped channel 10 as in Applicants' claimed invention and, thus, do not eat into the rod *outside the pressure fixing device*. Accordingly, JACKSON fails to disclose protruding portions that "eat into the rod portion in both end sides of the circular arc rod engagement portion outside the pressure fixing device", as recited in claim 1; and small projections that are "configured to eat into the rod, the small projections being provided on both sides of the groove portion", as recited in claim 3.

Secondly, the ridges 17 of JACKSON do not extend in a direction substantially perpendicular to the longitudinal direction of the vertebra connecting member. In this regard, as clearly shown in figures 1 and 2 of the JACKSON

patent, each ridge 17 extends in a direction parallel to the longitudinal direction of the spinal rod 15. As pointed out by Applicants and by the Examiner (i.e., "while yes, the elements (17) extend parallel to the rod"), the ridges 17 extend in a direction parallel to the rod. Each ridge 17 has a length, a longitudinal direction of extension. However, contrary to the Examiner's position (i.e., they "ALSO Even individually, they would extend extend perpendicular as a group. perpendicular to the rod albeit much less than their length"), the rods do not extend in a direction perpendicular to the rod. In this regard, Applicants point out that the ridges 17 are arranged side by side in a row, which row extends along the lower curved edge of the channel. However, the claims recite protruding portions and small projections "extending in a direction substantially perpendicular to a longitudinal direction of the vertebra connecting member", the claims do not recite a group of protruding portions and a group of small projections extending perpendicular to the longitudinal direction. Moreover, even assuming, arguendo, that the row may be described as extending in a direction substantially perpendicular to the longitudinal direction of the rod, each ridge 17 itself does not extend substantially perpendicular to the longitudinal direction of In this regard, Applicants respectfully submit that the Examiner's the rod. position that the ridges extend both in the parallel direction and the perpendicular direction is not reasonable. In this regard, Applicants point out that the elements of JACKSON are ridges, which can extend in one direction only. Otherwise, the resulting element could not fairly be described as a ridge. Accordingly, the ridges cannot fairly be described as extending in a direction substantially

P24196.A10

perpendicular to the longitudinal direction of the rod. Moreover, the text of the

JACKSON patent confirms this since column 4, lines 21-23 of JACKSON

describes that the ridges 17 "extend from a first or front face 18 to a second or

rear face 19 of the bone screw head 7". Therefore, JACKSON fails to disclose

"protruding portions extending in a direction substantially perpendicular to a

longitudinal direction of the vertebra connecting member", as recited in claim 1;

and "small projections extending in a direction substantially perpendicular to a

longitudinal direction of the rod", as recited in claim 1.

It is clear from the above that the JACKSON patent fails to disclose each

and every element of claims 1 and 3, and thus the rejection under 35 U.S.C. §

102(b) over JACKSON is improper, and withdrawal thereof is respectfully

requested. Moreover, Applicants respectfully submit that the rejection of claim 2,

which depends from claim 1, is also improper for the above noted reasons, and

withdrawal thereof is respectfully requested.

Reconsideration of the outstanding Final Official Action, and allowance of

the present application and all of the claims therein are respectfully requested

and now believed to be appropriate. Should there be any questions, the

Examiner is invited to contact the undersigned at the below listed number.

Respectfully Submitted,

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5